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MESSAGE

Commissioner for Patents
Washington, DC 20231

Supplemental Reply in 09/125,887

15 Total pages

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TRANSMISSION PROBLEMS: 202-220-6000

PATENT
Atty Docket: EX96002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Thierry BOON-FALLEUR

Appl. No.: 09/125,887

Filed: October 5, 1998

For: RECOMBINANT ADENOVIRAL VECTORS FOR HUMAN TUMOR GENE THERAPY AND CELLS CONTAINING THEM (as amended)

Art Unit: 1632

Examiner: A. Beckerleg

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On September 7, 2000 ,

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Supplemental Reply

Applicants request consideration of the supplemental arguments and evidence presented here. As a complete and timely response to the outstanding Office Action of December 23, 1999 (Paper No. 6) has already been filed, no extension of time fees or requests for extension of time are necessary to enter and consider this paper. If, however, any extensions of time are required or any fees are due in order to enter or consider this paper, applicants hereby request any

extensions or petitions necessary and the Commissioner is hereby authorized to charge our Deposit Account # 50-1273 for any associated fees.

Claims 20-40 are pending and are being examined.

In Paper No. 6, the PTO asserted that exogenous IL-2 may be required to make the adenoviral vectors operate as therapeutically effective treatments for cancer (*see* pages 3-4). Applicants have already addressed the fact that the appropriate standard is not therapeutic effectiveness as the FDA requires. Applicants submit the enclosed document, Siders *et al.* (PTO Form 1449 provided), showing that one skilled in the art would not consider exogenous IL-2 as a requirement for generating the anti-tumor response. In Siders *et al.*, IL-12 is discussed as a cytokine, expressed by antigen presenting cells, which promotes anti-tumor activity and development of tumor-destroying T cells, NK cells, and/or macrophages (*see* pages 5465-66). The vectors described, claimed, and recited in the claims here would, as one of skill in the art understands, promote the same response through activation of the endogenous IL-12 discussed in Siders *et al.* Thus, one skilled in the art would not presume that exogenous IL-2 is required for the vectors here to produce anti-tumor responses.

Furthermore, Siders *et al.* demonstrates that systemic, i.v. administration of the adenoviral vectors creates the desired effect on the immune system (*see* Figure 2 and page 5468). Thus, one skilled in the art would not need additional data addressing the route of administration of the claimed and recited vectors. The specification already shows intraperitoneal and subcutaneous injections.

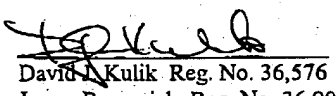
Accordingly, applicants respectfully submit that the § 112, first paragraph, rejection should be withdrawn.

V. Conclusion

Applicants believe that this application is now in condition for allowance. If the Examiner believes that prosecution might be furthered by discussing the application with Applicants' representatives, in person or by telephone, we would welcome the opportunity to do so.

Respectfully submitted,
Brobeck, Phleger & Harrison LLP

Date: September 7, 2000

By: 
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Enclosures: From PTO-1449
Siders *et al.* document